S. 725

IN THE HOUSE OF REPRESENTATIVES

 $$\operatorname{\mathsf{APRIL}}$ 26, 1994 Referred to the Committee on Energy and Commerce

AN ACT

To amend the Public Health Service Act to provide for the conduct of expanded studies and the establishment of innovative programs with respect to traumatic brain injury, and for other purposes.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,

1	SECTION 1. PROGRAMS OF CENTERS FOR DISEASE CON-
2	TROL AND PREVENTION.
3	Part B of title III of the Public Health Service Act
4	(42 U.S.C. 241 et seq.), as amended by section 703 of
5	Public Law 103-183 (107 Stat. 2240), is amended by in-
6	serting after section 317F the following section:
7	"PREVENTION OF TRAUMATIC BRAIN INJURY
8	"SEC. 317G. The Secretary, acting through the Di-
9	rector of the Centers for Disease Control and Prevention,
10	may carry out projects to reduce the incidence of trau-
11	matic brain injury. Such projects may be carried out by
12	the Secretary directly or through awards of grants or con-
13	tracts to public or nonprofit private entities. The Sec-
14	retary may directly or through such awards provide tech-
15	nical assistance with respect to the planning, development,
16	and operation of such projects.
17	"(b) Certain Activities.—Activities under sub-
18	section (a) may include—
19	"(1) the conduct of research into identifying ef-
20	fective strategies for the prevention of traumatic
21	brain injury; and
22	"(2) the implementation of public information
23	and education programs for the prevention of such
24	injury and for broadening the awareness of the pub-
25	lic concerning the public health consequences of such
26	injury.

1	"(c) Coordination of Activities.—The Secretary
2	shall ensure that activities under this section are coordi-
3	nated as appropriate with other agencies of the Public
4	Health Service that carry out activities regarding trau-
5	matic brain injury.
6	"(d) Definition.—For purposes of this section, the
7	term 'traumatic brain injury' means an acquired injury
8	to the brain. Such term does not include brain dysfunction
9	caused by congenital or degenerative disorders, nor birth
10	trauma, but may include brain injuries caused by anoxia
11	due to near drowning. The Secretary may revise the defi-
12	nition of such term as the Secretary determines nec-
13	essary.".
14	SEC. 2. PROGRAMS OF NATIONAL INSTITUTES OF HEALTH.
15	Section 1261 of the Public Health Service Act (42
16	U.S.C. 300d-61) is amended—
17	(1) in subsection (d)—
18	(A) in paragraph (2), by striking "and"
19	after the semicolon at the end;
20	(B) in paragraph (3), by striking the pe-
21	riod and inserting "; and; and
22	(C) by adding at the end the following
23	paragraph:
24	"(4) the authority to make awards of grants or
25	contracts to public or nonprofit private entities for

1	the conduct of basic and applied research regarding
2	traumatic brain injury, which research may in-
3	clude—
4	"(A) the development of new methods and
5	modalities for the more effective diagnosis
6	measurement of degree of injury, post-injury
7	monitoring and prognostic assessment of head
8	injury for acute, subacute and later phases of
9	care;
10	"(B) the development, modification and
11	evaluation of therapies that retard, prevent or
12	reverse brain damage after acute head injury
13	that arrest further deterioration following in-
14	jury and that provide the restitution of function
15	for individuals with long-term injuries;
16	"(C) the development of research on a con-
17	tinuum of care from acute care through reha-
18	bilitation, designed, to the extent practicable, to
19	integrate rehabilitation and long-term outcome
20	evaluation with acute care research; and
21	"(D) the development of programs that in-
22	crease the participation of academic centers of
23	excellence in head injury treatment and reha-

bilitation research and training."; and

24

1	(2) in subsection (h), by adding at the end the
2	following paragraph:
3	"(4) The term 'traumatic brain injury' means
4	an acquired injury to the brain. Such term does not
5	include brain dysfunction caused by congenital or
6	degenerative disorders, nor birth trauma, but may
7	include brain injuries caused by anoxia due to near
8	drowning. The Secretary may revise the definition of
9	such term as the Secretary determines necessary.".
10	SEC. 3. PROGRAMS OF HEALTH RESOURCES AND SERVICES
11	ADMINISTRATION.
12	Part E of title XII of the Public Health Service Act
13	(42 U.S.C. 300d-51 et seq.) is amended by adding at the
14	end the following section:
15	"SEC. 1252. STATE GRANTS FOR DEMONSTRATION
16	PROJECTS REGARDING TRAUMATIC BRAIN
17	INJURY.
18	"(a) IN GENERAL.—The Secretary, acting through
19	the Administrator of the Health Resources and Services
20	Administration, may make grants to States for the pur-
21	pose of carrying out demonstration projects to improve ac-
22	cess to health and other services regarding traumatic
23	brain injury.
24	"(b) State Advisory Board.—

1	"(1) IN GENERAL.—The Secretary may make a
2	grant under subsection (a) only if the State involved
3	agrees to establish an advisory board within the ap-
4	propriate health department of the State or within
5	another department as designated by the chief exec-
6	utive officer of the State.
7	"(2) Functions.—An advisory board estab-
8	lished under paragraph (1) shall advise and make
9	recommendations to the State on ways to improve
10	services coordination regarding traumatic brain in-
11	jury. Such advisory boards shall encourage citizen
12	participation through the establishment of public
13	hearings and other types of community outreach
14	programs.
15	"(3) Composition.—An advisory board estab-
16	lished under paragraph (1) shall be composed of—
17	"(A) representatives of—
18	"(i) the corresponding State agencies
19	involved;
20	"(ii) public and nonprofit private
21	health related organizations;
22	"(iii) other disability advisory or plan-
23	ning groups within the State:

1	"(iv) members of an organization or
2	foundation representing traumatic brain
3	injury survivors in that State; and
4	"(v) injury control programs at the
5	State or local level if such programs exist;
6	and
7	"(B) a substantial number of individuals
8	who are survivors of traumatic brain injury, or
9	the family members of such individuals.
10	"(c) Matching Funds.—
11	"(1) In general.—With respect to the costs to
12	be incurred by a State in carrying out the purpose
13	described in subsection (a), the Secretary may make
14	a grant under such subsection only if the State
15	agrees to make available, in cash, non-Federal con-
16	tributions toward such costs in an amount that is
17	not less than \$1 for each \$2 of Federal funds pro-
18	vided under the grant.
19	"(2) Determination of amount contrib-
20	UTED.—In determining the amount of non-Federal
21	contributions in cash that a State has provided pur-
22	suant to paragraph (1), the Secretary may not in-
23	clude any amounts provided to the State by the Fed-

24

eral Government.

- 1 "(d) Application for Grant.—The Secretary may
- 2 make a grant under subsection (a) only if an application
- 3 for the grant is submitted to the Secretary and the appli-
- 4 cation is in such form, is made in such manner, and con-
- 5 tains such agreements, assurances, and information as the
- 6 Secretary determines to be necessary to carry out this sec-
- 7 tion.
- 8 "(e) Coordination of Activities.—The Secretary
- 9 shall ensure that activities under this section are coordi-
- 10 nated as appropriate with other agencies of the Public
- 11 Health Service that carry out activities regarding trau-
- 12 matic brain injury.
- 13 "(f) Report.—Not later than 2 years after the date
- 14 of the enactment of this section, the Secretary shall sub-
- 15 mit to the Committee on Energy and Commerce of the
- 16 House of Representatives, and to the Committee on Labor
- 17 and Human Resources of the Senate, a report describing
- 18 the findings and results of the programs established under
- 19 this section, including measures of outcomes and
- 20 consumer and surrogate satisfaction.
- 21 "(g) Definition.—For purposes of this section, the
- 22 term 'traumatic brain injury' means an acquired injury
- 23 to the brain. Such term does not include brain dysfunction
- 24 caused by congenital or degenerative disorders, nor birth
- 25 trauma, but may include brain injuries caused by anoxia

1	due to near drowning. The Secretary may revise the defi-
2	nition of such term as the Secretary determines necessary.
3	"(h) Authorization of Appropriations.—There
4	are authorized to be appropriated to carry out this section
5	such sums as may be necessary for each of the fiscal years
6	1995 through 1997.".
7	SEC. 4. STUDY; CONSENSUS CONFERENCE.
8	(a) Study.—
9	(1) IN GENERAL.—The Secretary of Health and
10	Human Services (in this section referred to as the
11	"Secretary"), acting through the appropriate agen-
12	cies of the Public Health Service, shall conduct a
13	study for the purpose of carrying out the following
14	with respect to traumatic brain injury:
15	(1) In collaboration with appropriate State and
16	local health-related agencies—
17	(A) determine the incidence and prevalence
18	of traumatic brain injury; and
19	(B) develop a uniform reporting system
20	under which States report incidences of trau-
21	matic brain injury, if the Secretary determines
22	that such a system is appropriate.
23	(2) Identify common therapeutic interventions
24	which are used for the rehabilitation of individuals

1	with such injuries, and shall, subject to the availabil-
2	ity of information, include an analysis of—
3	(A) the effectiveness of each such interven-
4	tion in improving the functioning of individuals
5	with brain injuries;
6	(B) the comparative effectiveness of inter-
7	ventions employed in the course of rehabilita-
8	tion of individuals with brain injuries to achieve
9	the same or similar clinical outcome; and
10	(C) the adequacy of existing measures of
11	outcomes and knowledge of factors influencing
12	differential outcomes.
13	(3) Develop practice guidelines for the rehabili-
14	tation of traumatic brain injury at such time as ap-
15	propriate scientific research becomes available.
16	(2) Dates certain for reports.—
17	(A) Not later than 18 months after the
18	date of the enactment of this Act, the Secretary
19	shall submit to the Committee on Energy and
20	Commerce of the House of Representatives, and
21	to the Committee on Labor and Human Re-
22	sources of the Senate, a report describing the
23	findings made as a result of carrying out para-
24	graph (1)(A).

- 1 (B) Not later than 3 years after the date 2 of the enactment of this Act, the Secretary shall 3 submit to the Committees specified in subpara-4 graph (A) a report describing the findings made 5 as a result of carrying out subparagraphs (B) 6 and (C) of paragraph (1).
- 7 (b) Consensus Conference.—The Secretary, act8 ing through the Director of the National Center for Medi9 cal Rehabilitation Research within the National Institute
 10 for Child Health and Human Development, shall conduct
 11 a national consensus conference on managing traumatic
 12 brain injury and related rehabilitation concerns.
- 13 (c) Definition.—For purposes of this section, the
 14 term "traumatic brain injury" means an acquired injury
 15 to the brain. Such term does not include brain dysfunction
 16 caused by congenital or degenerative disorders, nor birth
 17 trauma, but may include brain injuries caused by anoxia
 18 due to near drowning. The Secretary may revise the defi19 nition of such term as the Secretary determines necessary.
- 20 (d) AUTHORIZATION OF APPROPRIATIONS.—There 21 are authorized to be appropriated to carry out this section 22 such sums as may be necessary for each of the fiscal years 23 1995 through 1997.

SEC. 5. MAPLE SYRUP.

- 2 (a) Preemption.—Section 403A(a) of the Federal
- 3 Food, Drug, and Cosmetic Act (21 U.S.C. 343-1(a)) is
- 4 amended—
- 5 (1) in paragraph (1), by inserting at the end
- 6 the following: "except that this paragraph does not
- 7 apply to a standard of identity of a State or political
- 8 subdivision of a State for maple syrup which is of
- 9 the type required by sections 401 and 403(g),",
- 10 (2) in paragraph (2), by inserting at the end
- the following: "except that this paragraph does not
- apply to a requirement of a State or political sub-
- division of a State which is of the type required by
- section 403(c) and which is applicable to maple
- 15 syrup,", and
- 16 (3) in paragraph (3), by inserting at the end
- the following: "except that this paragraph does not
- apply to a requirement of a State or political sub-
- division of a State which is of the type required by
- section 403(h)(1) and which is applicable to maple
- 21 syrup,".
- 22 (b) Procedure.—Section 701(e)(1) (21 U.S.C.
- 23 371(e)(1)) is amended by striking "or maple syrup (regu-

- 1 lated under section 168.140 of title 21, Code of Federal
- 2 Regulations).".

Passed the Senate April 21 (legislative day, April 11), 1994.

Attest:

MARTHA S. POPE,

Secretary.